

REMARKS

The Examiner provides a number of rejections and we list them here in the order in which they are addressed:

I. Written Description Rejections

- A. Claims 75-110 are rejected under 35 USC § 112 ¶ 1 as allegedly containing subject matter not described in the specification to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention.
- B. Claims 75-110 are rejected under 35 USC § 112 ¶ 1 as allegedly being indefinite.

II. Anticipation Rejections

- A. Claims 75, 78, 79, 81, 82, 84, 87-89, 91, 92, 94, 95, 97, 100, 101, and 106 are rejected under 35 USC § 102(b) as allegedly anticipated by Fukamizu *et al.*, Biochim Biophys Res. Comm. 199:183-190 (1994).
- B. Claims 75, 78-83, 87-89, 91-96, 100, 102, and 107 are rejected under 35 USC § 102(b) as allegedly anticipated by Semenza *et al.*, Annals NY Acad Sci. 718:41-49 (1994).
- C. Claims 75, 78-83, 87-89, 91-96, 100, 102, and 107 are rejected under 35 USC § 102(a) as allegedly anticipated by Haidar *et al.*, J. Structural Biol. 118:220-225 (April 1997).

D. Claims 75, 78-83, 87-89, 91-96, 100, 103, and 108 are rejected under 35 USC § 102(b) as allegedly anticipated by Simonet *et al.*, J. Biol. Chem. 265:10809-10812 (1990).

III. The Examiner requests amendment of the invention title.

E. Claims 75, 78-82, 86-89, 91, 92, 94, 95, 99, 100, 103, and 108 are rejected under 35 USC § 102(e) as allegedly anticipated by Boyle *et al.*, United States Patent No. 6,613,544 (Filed: 1995).

I. The Claims Comply With 35 USC § 112

The Examiner has asserted several rejections to claims 75-110 under either 35 USC § 112 ¶¶ 1,2. The Applicants disagree. Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have canceled Claims 75-110 and added new Claims 111-116 that are believed consistent with the Examiner's above positions. The Applicants' specification provides examples of genes comprising promoters that direct kidney protein expression. For example: i) whey acidic protein (Example 1); ii) uromodulin (pg. 21 ln 3 - 19); iii) uroplakin (pg. 22 ln 19 - 31); iv) osteopontin (pg. 22 ln 5 - 12); v) nephrocalcin (pg. 23 ln 24 - pg. 24 ln 4); and vi) aquaporin (pg. 24 ln 20 - pg. 25 ln 2). Thus, the new claims are properly supported.

The Applicant wish the Examiner to note that these new claims reflect the Examiner's own admissions in this, and previous, Office Actions:

- i) ... the specification provides adequate written description for the WAP [whey acidic protein] and uroplakin promoters as being capable of secreting exogenous proteins into the urine of transgenic mammals. *Office Action Mailed 06/17/04 pg. 5.*
- ii) In conclusion, the 5' regulatory sequences should be limited to the WAP promoter, the uroplakin promoter or promoters that cause secretion of

exogenous protein into the urine of the transgenic animal. *Office Action Mailed 06/17/04 pg. 13.*

- iii) the specification [is] ... enabling for a transgenic non-human mammal whose genome comprises a transgene comprising a nucleic acid sequence encoding a protein operatively linked to a promoter that causes secretion of the protein into the urine of the transgenic mammal, wherein said protein is expressed and secreted into the urine of said transgenic non-human mammal and a method of producing a protein in the urine ... *Office Action Mailed 06/17/04 pg. 17.*
- iv) In conclusion, the regulatory sequences should be limited to the WAP promoter, the uroplakin promoter or promoters that direct expression of the exogenous protein in cells of the urinary tract of the mammal. *Office Action Mailed 06/05/01 pg 16.*

The Applicants respectfully request the Examiner to withdraw the present rejection.

II. The Claims Are Not Anticipated

Since the claims have been amended (see above) and now specify promoters that are not taught in the cited art, the Applicants now consider these rejections moot. The Applicants now respectfully request the Examiner withdraw the present rejection.

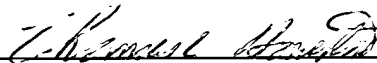
III. The Title Reflects The Claimed Embodiment

The Examiner states that "The title of the application should be changed to more closely reflect the claimed invention" *Office Action, pg. 1.* The Applicants disagree but have modified the title in the manner suggested by the Examiner. The title now is requested to read "Compositions And Methods For Protein Expression In Transgenic Animal Urine". The Applicants now respectfully request the Examiner withdraw the present objection.

CONCLUSION

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

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